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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/013,980	11/05/2001	Gust H. Bardy	032580.0060.CIP	3720

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT PAPER NUMBER

3762

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/013,980

Applicant(s)

BARDY ET AL.

Examiner

Kennedy Schaetzle

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 59-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 59-65, 68-71, 75-77, 79-84 and 86 is/are rejected.
- 7) ☒ Claim(s) 66, 67, 72-74, 78 and 85 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 18, 2005 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 59-62, 68-71, 75, 76, 79-83 are rejected under 35 U.S.C. 102(b) as being anticipated by Heilman et al. (Pat. No. 4,030,509).

Regarding claim 1, Heilman et al. disclose an implantable lead electrode assembly comprising an electrode 102 having a proximal and a distal end, and top and bottom surfaces, a backing layer 110 positioned over the top of the electrode, and a fin 112 (and/or 118), wherein the backing layer forms the fin and the fin projects from the backing layer. The intended use statement in the preamble was considered, but deemed insufficient to saliently distinguish over the apparatus of Heilman et al. in the absence of any structural recitation in the body of the claim limiting the device to such placement. Related comments apply to claims 75 and 81.

Regarding claim 59, see Fig. 6.

Regarding claim 60, see Figs. 5-7.

Regarding claims 61 and 80, see lead 104.

Regarding claims 62, 69 and 70, see col. 8, lines 25-28.

Regarding claims 68 and 79, the examiner considers the fin(s) 112 to have proximal and distal ends (e.g., one might consider the right-most element 112 shown in Fig. 6 to be a proximal end of the fin with the left-most element 112 representing a distal end of the fin. The proximal end of the fin is sloped as shown by its rounded profile overlapping the electrode.

Regarding claim 71, see Fig. 6 where the flexible fin is shown folded over the electrode thereby reducing the height of the fin.

Regarding claim 76, see Fig. 6.

Regarding claim 82, the examiner considers elements 116 and 118 to constitute a fin including a rigid head 116 (note col. 8, lines 35-37) and a flexible connector 118 attaching the rigid head to the backing layer 110.

Regarding claim 83, the examiner considers the fin to be *movable* from a first position in which the rigid head extends substantially perpendicular from the electrode (see position of rigid head 116 in Fig. 6) to a second position in which the rigid head is substantially parallel to the electrode, by virtue of the fact that one can bend the tip 116 so that it lies parallel to the electrode. The term *movable* only requires that the element be capable of such positioning.

4. Claims 84 and 86 are rejected under 35 U.S.C. 102(b) as being anticipated by Rockland et al. (Pat. No. 4,010,758).

Concerning claim 84, Rockland et al. disclose an implantable lead electrode comprising an electrode 21 having a first face and a second face (inherent with any two or three dimensional object), a backing layer 26, 28 disposed over the first face of the electrode, and an appendage 18, 24 disposed on the first face of the electrode and extending through the backing layer (note col. 4, lines 36-44). The electrode, backing layer and appendage are adapted for implantation in a patient.

Concerning claim 86, Rockland et al. state that the appendage 18 can be made of platinum iridium (col. 4, lines 14-22). Claim 86 does not require that the appendage be made entirely of platinum or titanium (even if such an amendment were to be made, the examiner would not consider the claim allowable given that such materials are commonplace in the medical electrode lead arts).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 63-65 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilman et al. (Pat. No. 4,030,509).

Concerning claim 63, the examiner takes Official Notice that polyurethane backing layers for lead electrode assemblies are old and well known in the medical arts. Such material is biocompatible, insulative, and easy to manufacture –all desirable and necessary qualities for the backing layer of Heilman et al.. The courts have long determined that the use of a known material based on its suitability for the intended purpose is obvious.

Regarding claims 64 and 77, the examiner takes Official Notice that it is old and well-known in the medical electrode arts to utilize covers (i.e., packages) for implantable lead assemblies in order to maintain a sterile environment prior to implant and protect the delicate lead assembly. Those of ordinary skill in the art would have considered the use of a cover disposed over the backing layer and fin to be blatantly obvious to prevent contamination. It should further be noted that since the applicants have chosen not to invoke the 6th paragraph of §112, the examiner is not restricted to find covers that are the same or equivalent to those set forth in the present specification. Any element that can act as a cover would be of relevance to the claim.

Claim 65 represents a product-by-process claim in that the applicants appear to be defining the cover by the way it is manufactured (e.g., molded). The examiner takes Official Notice that covers or packages for containing medical electrodes may be of molded construction. The type of construction would simply depend upon the type of material used to construct the cover, and on the design constraints imposed upon any medical electrode cover (e.g., cost, durability, function, etc.).

Allowable Subject Matter

7. Claims 66, 67, 72-74, 78 and 85 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claim 66, there is no suggestion in the prior art of record for modifying the Heilman et al. reference to include the recited folded, indented fin-forming region and recited backing layer.

With regard to claim 72, the prior art of record fails to disclose the recited substantially tubular fin.

The reinforcing polymer of claim 78 is not suggested for placement between the fin and cover of the implantable lead electrode.

The recited rod with first and second extensions attached to the first face of the electrode and loop therebetween is not disclosed in the prior art of record.

Conclusion


8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaeztle whose telephone number is 571 272-4954. The examiner can normally be reached M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached M-F at 571 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
April 19, 2005


KENNEDY SCHAEZTLE
PRIMARY EXAMINER